Recall

- Described in 21 CFR 7.40
- Voluntary
- Mandatory
Recall

- Effective way of removing violative product
- Requires classification
- Caveat
Process

- Generated by sponsor
- Reported to District Office
- Reported to CDRH
Process

- Preliminary recommendation
- Documents to CDRH by fed ex
- Early alert
Process

• Logged into Office of Compliance
• Transferred to OIVD
• Triaged by Deputy -- James Woods
• Assigned to CSO -- 5 in OIVD
Incoming Document

- Recall recommendation review form
- M204 computer sheet
- Recommendation
- Supporting documents
CSO Responsibilities

• Determine compliance with premarket requirements
• Approve or disapprove firm’s action as recall
• Triage – precedent or HHE
• Classify firm’s action
Recall Procedure

• Confirm marketing status
• Determine product code and panel code
Recall Procedure

- Is firm’s action appropriate
- Are other remedies appropriate
- Market withdrawal
- Stock recovery
- Safety alert
If Recall

- Reason
- Health consequences
- Precedent
- Classification and course of action
Reason

- Clear description
- Root cause identification
- Obvious
- Not so obvious
- Real time interactions
Health Hazard Evaluation

- Disease or injury already occurred
- Disease or injury could occur
- Vulnerable populations
- Degree of risk
- Likelihood of risk
- Consequences
Health Hazard Evaluation

• Search for precedent
• Replace HHE
• Inform HHE
Precedent

- Product
- Problem
- Risk to health
- Equivalency
Precedent

• Recalls on the web
• Web data base
• 2000 +
Precedent Search

- Keywords
- Product
- Problem
- Component
- Health effect
Precedent Search

• Keywords
• Product -- glucose meter
• Problem -- reading failure
• Component -- software
• Health effect -- delayed treatment
Precedent Search

- Perfect match
- Equivalent risk, different device
- No equivalent match
Growing Data Base

- Product
- Product details
- Reason
- Complaints
- Hazard description
Growing Data Base

• Save time and money
• Consistency
• Learning
HHE

- No precedent
- Uncertain precedent
- Class I precedent
- High risk device
HHE

- Team approach
- CSO
- Medical Officer
- Reviewer(s)
- District regulatory scientists
HHE

- Coordinating medical officer
- Five additional medical officers
- Cohesive group
- Err on over review
HHE

- Consistent approach
- Neutral to actions taken
- As if hazard were ongoing
- Factual
## Health Hazard Evaluation

**Center for Devices and Radiological Health**  
**Office of Compliance**

<table>
<thead>
<tr>
<th>Date:</th>
<th>Consumer Safety Officer:</th>
</tr>
</thead>
</table>

### I. Product Data

<table>
<thead>
<tr>
<th>Panel/Product Code:</th>
<th>Product Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model:</th>
<th>Lot/Serial Numbers:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Marketing Status** (510(k), PMA, pre-amendment, exempt):

<table>
<thead>
<tr>
<th>Volume in Distribution or Use:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Manufacturer and Recalling Firm (specify):**

<table>
<thead>
<tr>
<th>Product Description: (A description of the product and its intended use)</th>
</tr>
</thead>
</table>
Complaint, Incident, Problem Reported:

<table>
<thead>
<tr>
<th>Number of Complaints, Incidents, Problems Reported:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Injuries:</td>
</tr>
<tr>
<td>Source of Reports:</td>
</tr>
</tbody>
</table>

Description of the Hazard/Problem Caused by the Defect/Malfunction or Error in Use:

Device or Other Product Related Factors (Design, production, QC, labeling). Possibly Contributing to the Health Hazard Situation:

Use Related, User or Human Performance Contributing Factors:

Population at Greater Risk: (e.g., children, elderly, pregnant women, immunocompromised, etc.)

Immediate and/or Long Range Health Consequences of the Hazard (specify):
### III. Health/Risk Index – Place a check in the appropriate box

**Assessment of the Likelihood of Occurrence of the Potentially Hazardous Event:**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remote</td>
<td>0</td>
</tr>
<tr>
<td>Rare</td>
<td>+1</td>
</tr>
<tr>
<td>Occasional</td>
<td>+2</td>
</tr>
<tr>
<td>Frequent</td>
<td>+3</td>
</tr>
<tr>
<td>Continuously Occurring</td>
<td>+4</td>
</tr>
</tbody>
</table>

**Probability of Injury Occurring to the Population at Risk or Exposed:**

<table>
<thead>
<tr>
<th>Probability</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely Unlikely</td>
<td>0</td>
</tr>
<tr>
<td>Unlikely but Possible</td>
<td>+1</td>
</tr>
<tr>
<td>Likely</td>
<td>+2</td>
</tr>
<tr>
<td>Very Likely</td>
<td>+3</td>
</tr>
<tr>
<td>Extremely Likely</td>
<td>+4</td>
</tr>
</tbody>
</table>

**Severity of the Injury or Adverse Health Outcome (that might reasonably be expected to occur):**

<table>
<thead>
<tr>
<th>Severity</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>None (No adverse health consequences)</td>
<td>0</td>
</tr>
<tr>
<td>Limited (Transient, self-limiting illness or injury)</td>
<td>+1</td>
</tr>
<tr>
<td>Moderate (Significant impairment, but temporary/inversible)</td>
<td>+2</td>
</tr>
<tr>
<td>Severe (Serious injury, permanent impairment, irreversible)</td>
<td>+3</td>
</tr>
<tr>
<td>Life Threat (Life threatening, death could occur)</td>
<td>+4</td>
</tr>
</tbody>
</table>

**Hazard/Risk Index (obtained by adding the score of the above three variables):**

<table>
<thead>
<tr>
<th>Level</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>None/Negligible</td>
<td>0–3</td>
</tr>
<tr>
<td>Low</td>
<td>4–6</td>
</tr>
<tr>
<td>Moderate</td>
<td>7–9</td>
</tr>
<tr>
<td>High</td>
<td>10–12</td>
</tr>
</tbody>
</table>

**Comments:**

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**HEALTH HAZARD EVALUATION COMMITTEE - Please Print and Sign your Name Below:**

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office of Compliance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Officer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Officer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specialist</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Acquired Taste/Skill

- Class III - 50 to 60%
- Class II - 35+%
- Class I - 1 to 2%
Class I

• Reasonable possibility of serious harm
Class II

- Reversible harm
- Remote chance of serious harm
Class III

• Not likely to cause harm
Context of Use

- IVDs often used with other information items
- IVDs often used with QC procedures
- IVDs often have labeling caveats
- IVDs may tolerate near misses (especially if test is quantitative)
Public Record

• April 2003
• Broad menu -- glucose, hep C, AFP, PT
• Big numbers
• Errors can be big
Result of HHE/Precedent

• Assessment of risk
• Classification
• Course of action
Recall Plan

- Classify -- assessment of impact on health
- Evaluate strategy
- Evaluate corrective action plan
Recall Plan

- Depth of recall
- Public Warning
- Effectiveness checks
Corrective Action Plan

• Root cause
• Corrective action
• Repair of quality system regulations
• Hardest word and last word
Total Product Life Cycle

- OIVD and all of CDRH
- Recalls a useful tool
- Recalls a valuable resource
- Knowledge management
Good Science